Green Ribbon Science Panel

REPORT OUT
***Subcommittee #2*: Tiered Alternatives Assessments**
June 2 and 14, 2011 Teleconferences

Subcommittee #2 Chairperson --- Jeff Wong, Ph.D.

Subcommittee #2 members:

- Bruce Cords, Ph.D.
- Richard Denison, Ph.D.
- Michael Kirschner
- Richard Liroff, Ph.D.
- Kelly Moran, Ph.D.
- Megan Schwarzman, M.D.
- Anne Wallin, Ph.D.

NOTE: In general, the notes set forth in this report out are presented in the sequence of the subcommittee's discussions rather than strictly by topic. Repeated comments that applied to multiple topics are generally only presented once in these notes. (The subcommittee also discussed some of the questions or aspects of the issues before them in the context of two process graphs that were distributed to members.)

DTSC's OVERARCHING COMMENTS REGARDING TIERED AA CONCEPTS:

- DTSC stated that it views the term "Life Cycle Assessment tool" as used in the statute as consisting of both qualitative and quantitative tools. It was noted that the statute requires these tools to be transparent and easy to use, which supports DTSC's views. (There was a comment supporting this interpretation.)

- DTSC pointed out that essentially three different approaches/bases for the tiering of AAs had been discussed, and noted that some or all of these could be used as a screening approach. These were:
    1. Robustness of review/analysis
    2. Number of (A)-(M) factors evaluated
    3. Number of life cycle segments considered

- There was a comment from the subcommittee suggesting a fourth basis for tiered AAs. That was that the range of alternatives considered in the AA would vary. There could be a tiered approach to determining which alternatives warrant further analysis. One would start by screening out any alternatives that did not address the concern that led to the chemical being identified as a COC in the first place.

Question #2A: Which of the below, or other, conceptual approaches should be used for developing a tiered AA process?

Concept #1 would not require consideration of the full range of factors specified in Health and Safety Code (HSC) section 25253 (see page 5 for the list of factors) for the lower tier/less complex AAs. An example might be the Design for the Environment (DfE) process. Perhaps this approach could be accomplished by allowing a manufacturer to conduct a lower tier AA in conjunction with the manufacturer's agreement to implement a DTSC-specified regulatory response upon completion of the lower tier AA.

Concept #2 would require that each tier of an AA consider all of the AA factors set out in HSC section 25253, but there would be different levels of rigor for the data submittal and evaluation that are required. An example of a three-tiered approach based on a document entitled "Tiered Alternatives Assessment Concept Model" (prepared by GRSP members Ann Blake, Ken Geiser, and Kelly Moran, April, 2010) was provided to the subcommittee members.

- There was an analogy made to a U.S. EPA pesticide registration program. A concern was raised that "deal-making" is a cause for concern in the event that the rigor of the AA is linked to the manufacturer's "agreement to implement a DTSC-specified regulatory response". Transparency is necessary for interactions between the government and the regulated entity, and the regulatory response is not considered to be at the discretion of the manufacturer.
- One way to approach streamlining of the AA is to invoke principles from alternatives assessment and lifecycle assessment frameworks:
  - *Factors that are not significantly different:* Require a level of analysis sufficient but not more than needed to establish that a given factor does not significantly differ among alternatives being compared, and can be safely assumed not to be dispositive in selecting among them.
  - *Avoid paralysis by analysis/Diminishing returns:* Similarly, limit the depth of analysis of a given factor to that needed to capture its differential contribution to the alternatives being compared, without forcing further quantitative analysis that would shed little additional light on the comparison (akin to a 90:10 rule).
- A suggestion was made that one should pick out the most relevant (A)-(M) factors for any given product's health and environmental impacts. The factors would be scaled to delineate the degree to which that factor contributes to the reason for designating the chemical or product as a COC/priority product.
- The above suggestion was discussed in the context of an analogous "focusing out" concept embedded within CEQA, by which project developers focus their Environmental Impact Reports (EIRs) on certain impact areas, based on "substantial evidence" in the record and justification from the Initial Study process.
- A comment was made that some of the (A)-(M) factors have little to no direct relationship to many of the regulatory response(s) outlined in the statute.

Reference was made to Tim Malloy's document that groups the (A)-(M) factors into five categories that could, in turn, help set priorities among the factors.

- Another comment noted that there needs to be some attention paid to the cost of preparing an AA/LCA --- there should not be an unreasonably expensive document.
- A comment was made that the aim of a tiered AA is to relatively quickly determine how relevant a factor the availability of alternatives is in identifying whether and how to regulate the COC/priority product. If availability of alternatives is not relevant, needed, or helpful for initial determinations, a more focused follow-up assessment would not be needed or required — at least initially.
- The AA could be streamlined by considering only the (A)-(M) factors that are most relevant to the need for alternatives (i.e., the major drivers of the chemical/ product designation as a COC/priority product).
- Once alternatives are screened out that do not ameliorate the reason that a chemical is identified as a COC, then one would move to an examination of all of the (A)-(M) factors for the remaining alternatives.

Question #2B: What elements should be required to be included for each AA tier?

- Everything within Life Cycle Analysis needs to be addressed.
- First-tier AAs should be streamlined by applying three screening questions to each of the (A)-(M) factors. This approach provides an opportunity for DTSC to proceed to appropriate regulatory responses more expeditiously, pending a more in-depth assessment that could occur subsequently, where indicated. The three questions are:
    1. Is the factor a major contributor to the identification of the COC/priority product?
    2. Are there major differences in this factor between the current product and the alternative(s) being considered? If a factor is deemed a significant contributor to the prioritization of the chemical/product under consideration, the analysis should be focused by asking question 3 below.
    3. At what point in the COC/priority product life cycle is the factor relevant? (Another commenter suggested moving to a determination of whether or not a factor warrants further analysis without the use of this third criteria/factor.)
- All thought processes and information or lack thereof needs to be displayed.
- It was noted that manufacturers already consider factors (A), (B) and (M) (function/performance, useful life, and economic impacts) because they are important considerations to the manufacturer. All factors must at least be initially considered.
- Sequencing may allow for screening out some alternatives because they are no better with respect to a given factor than the COC. Criteria/guidance is needed to determine when something is not/cannot be a relevant alternative.

- Borrow from life cycle analysis --- look only at criteria with material differences across the alternatives.
- The intent of the process is subverted if we do not get to see entire range of alternatives that were considered.
- Key to keeping the process manageable is to support different levels of analysis and emphasis for the (A)-(M) factors based on relevance of the factors to the particular COC/priority product. It would be necessary to justify decisions (made by DTSC or the manufacturer) regarding the importance or lack thereof of any given factor.
- Technical performance and costs are internal issues for the manufacturer and should have a different, potentially less stringent level of transparency and weighting than other factors.
- Another comment agreed with the above point, but felt all these factors still need to be considered and justification provided for determinations made.
- Assessment ought to be able to focus on what is most relevant and impactful. There should be more robust information required for the factors that are deemed most important. Potential methods for accomplishing this are presented as the three screening questions discussed above.
- AA reports must include descriptions of the rationale, but need not be quantitative in all cases. Areas where there is significant uncertainty as to the potential impact of any one factor should be highlighted. There could be an iterative approach in which follow up work is done on elements of the analysis that have a high degree of uncertainty.
- Answers should be quantitative where data are available, and qualitative where they are not.
- There was a recommendation that the scope of required alternatives should include consideration of the potential that the COC could be eliminated from the product altogether.

Question #2C: What data or other information should be required to be obtained or developed and evaluated to support each AA tier?

- Not all criteria will have a lot of data. Some data will be claimed as trade secret.
- Need to keep scope/robustness of data required for AA linked with selection of an appropriate regulatory response.
- A truncated AA to get to a presumed regulatory response closes down opportunities to find broader solutions.
- Trade-off between full-blown AA versus expeditious actions was noted. Need to strike a balance between expeditious actions and best action.
- There was discussion of flow chart prepared by Kelly Moran. It was noted that intervening regulatory response is different in one proposal than another.
- A comment was made that the only link between AA and regulatory response is a temporal one.
- There was discussion of the question whether the AA "informs" the regulatory response or "dictates" the regulatory response. This discussion was based on the

view that many of the statutory regulatory responses are not directly related to information required in the AA or depend on its outcome.

- It was noted that not all regulatory responses are even relevant to whether or not an alternative exists (e.g. labeling, end-of-life management requirements).
- Robustness of review is important. All life cycle segments should be examined, but an initial narrower range of alternatives could be considered. If none, then move on to look at more alternatives.

Question #2D: What should be the circumstances or conditions for allowing a manufacturer to conduct a lower tier AA?

- All COCs/priority products and their alternatives should go through a tier one AA; only certain ones need to proceed to a more focused follow-up assessment.
- In narrowing the scope of a tier one AA, a distinction was drawn between decreasing the range of alternatives versus decreasing the range of (A)-(M) factors that are considered in the AA. Focus should be on the range of alternatives that address the primary reason the chemical was identified as a COC, and that account for the major differences among alternatives.
- A primary trigger is DTSC's decision as to the range of regulatory responses it sees as needed or desirable, the selection of which would be better informed by a more robust consideration of alternatives.
- Another way of framing this question is what should be the basis for requiring a more focused follow-up assessment. A manufacturer would conduct a more intensive follow-up assessment only if no obvious alternatives were found.
- There is a tension between the need for full information and the cost/time required to complete an AA. One approach would rely on existing data for initial analysis, then determine if there is a need for more focused follow-up. There should be a standard, such as "substantial evidence in the record".
- There should be focused follow-up on factors where data is lacking. Look at Proctor & Gamble decision tree re: higher levels of investment to fill data gaps and acquire more robust data.

Question #2E: How should lower tier AAs be linked to the different types of regulatory responses?

- Can the AA contribute to identifying non-essential uses of COC in priority products? One idea was to include among the alternatives considered the alternative of eliminating rather than replacing the COC; in this way the question of how essential the use of the COC is in the product would be elucidated.
- One thought was that manufacturers are driven by cost and that therefore the COC would always be "essential"; otherwise, the COC would not be in the priority product. However, an example was given of a specific fragrance added to a room freshener, and the case was made that this is a non-essential ingredient, if

other non-toxic scents are available. Should elimination of the COC responsible for the fragrance be one of the alternatives required to be considered?

- Leave open all regulatory responses after completion of the Tier I AA. Do not limit yourselves. Put bounds on the AA.
- There may be situations in which a regulatory response is needed that restricts use of the COC even if no alternative exists, due to high level of concern.

MISCELLANEOUS COMMENTS FROM SUBCOMMITTEE #2:

- Manufacturers do not always understand what happens to their products after they are sold. Simple models for this exercise are helpful. Perhaps all life cycle stages could be distilled down to: (i) Before Use, (ii) During Use, and (iii) After Use.
- Process needs to be simple. In order to make a comparison, there needs to be an analysis of the current COC. There will be a lot of data missing — even for one COC.

HSC Section 25253 Factors:

(A) Product function or performance
(B) Useful life
(C) Materials and resource consumption
(D) Water conservation
(E) Water quality impacts
(F) Air emissions
(G) Production, in-use, & transportation energy inputs
(H) Energy efficiency
(I) Greenhouse gas emissions
(J) Waste and end-of-life disposal
(K) Public health impacts *
(L) Environmental impacts
(M) Economic impacts

* Including impacts to sensitive subpopulations.